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May 24, 2019

Hon. Elizabeth A. Wolford
United States District Judge
United States District Court
for the Western District of New York
Kenneth B. Keating Federal Building
100 State Street
Rochester, New York 14614

Via ECF

Re: *Steuben Foods, Inc. v. Shibuya Hoppmann Corp. et al.*, No. 1:10-cv-00781

Dear Judge Wolford:

In response to this Court's text order of May 14, 2019, the Shibuya and Hood defendants write to address the significance of the May 8, 2019 Final Written Decision on Remand of the Patent Trial and Appeal Board ("PTAB") in Inter Partes Review ("IPR") No. 2014-01235. The PTAB's decision is consistent with the claim construction for the term "aseptically disinfecting" that Shibuya and Hood have advocated before this Court.

In its claim-construction analysis (at pages 11 to 13) the PTAB explains that it had originally construed the term "aseptic" to mean "aseptic to any applicable United States FDA standard, and in the absence of any such standard, aseptic assumes its ordinary meaning of free or freed from pathogenic microorganisms." The PTAB had originally construed "any applicable United States FDA standard" to include the requirement of 21 C.F.R. § 178.1005(d) that the final product have a hydrogen peroxide residue of less than 0.5 parts per million. The PTAB found that the particular prior art references that Nestle USA ("NUSA") relied upon in the IPR proceeding did not disclose that there would be a residual hydrogen peroxide of less than 0.5 parts per million. Accordingly, the PTAB originally found that the challenged claims of the '013 patent were patentable over the relied-upon prior art.

On appeal, the Federal Circuit reversed and held the PTAB's construction of "aseptic" to be erroneous because "any applicable United States FDA standard" included standards that are not unique to aseptic packaging. In particular, the Federal Circuit found that the residual hydrogen peroxide regulation of 21 C.F.R. § 178.1005(d) applies to all foodstuffs, not only those that are packaged aseptically; therefore, that regulation is not part of the meaning of "aseptic" as used in the '013 patent. *See* PTAB Decision at 12 & 32 n.25 (citing *Nestle USA, Inc. v. Steuben Foods, Inc.*, 686 F. App'x 917, 919 (Fed. Cir. 2017). The Federal Circuit remanded the matter for evaluation under the correct claim construction.

In its decision on remand, the PTAB again focused mainly on the residual hydrogen peroxide requirement. Most of the challenged claims did not require any particular level of residual hydrogen peroxide, so those claims were found to be unpatentable over the relied-upon prior art. In contrast, Claim 20 did require a particular level of residual hydrogen peroxide, so the PTAB found it to be patentable over the specific prior art references that NUSA had relied on because those references did not disclose the claimed level of residual hydrogen peroxide.

To save claims 18 and 19—two claims without a residual hydrogen peroxide requirement—from invalidation, Steuben argued that the relied-upon prior art did not show "at least a 6 log reduction in spore organisms" even though the prior art did show at least such a reduction in *clostridium botulinum* and *bacillus cereus*, both of which are spore organisms. PTAB Decision at 30-31. Steuben argued that the "FDA level of aseptic" required showing at least a 6-log reduction in a particular spore organism, *bacillus subtilis*, because (1) the only FDA-approved sterilant at the time the patent application was filed was hydrogen peroxide, and (2) *bacillus subtilis* is the test organism that the FDA uses to test for FDA levels of sterility when hydrogen peroxide is the sterilant, so that the FDA would not approve a system unless the requisite reduction in *bacillus subtilis* has been shown. *Id.* at 30.

The PTAB squarely rejected Steuben's argument and explained that the argument "mistakenly conflates 'FDA level of aseptic' with FDA approval and/or validation." *Id.* at 32. Although challenged claim 19 requires "aseptically disinfecting," the PTAB took pains to note that the claim "does not require the use of hydrogen peroxide or FDA approval." *Id.* at 32 & n.25. The PTAB criticized Steuben for failing to discuss whether the reduction in *bacillus subtilis* "is merely a requirement for FDA approval, *which is not claimed*, or whether there is a relevant regulation dealing with aseptic packaging, as required by the construction of 'aseptic.'" *Id.* at 33 (emphasis added).

These arguments that Steuben unsuccessfully advanced before the PTAB are strikingly similar to the arguments that GEA and NUSA have advanced before this Court: they argue that "aseptically disinfecting" cannot include disinfection using oxonia as a sterilant because hydrogen peroxide was the only FDA-approved sterilant when the patent application was filed. This Court should reject that argument, just as the PTAB rejected Steuben's similar argument, because "aseptically disinfecting" does not implicitly require meeting every requirement necessary to obtain FDA approval. The claims and written description of the patents-in-suit repeatedly refer to aseptically disinfecting using oxonia as a sterilant. Consequently, persons of ordinary skill in the art, at the time the patent applications were filed, would have understood "aseptically disinfecting" to include disinfecting using oxonia. As the PTAB concluded in rejecting Steuben's analogous argument, the mere fact that the FDA might not have approved such a system at the relevant time is not enough to overcome the unambiguous references in the patents to disinfecting using oxonia. NUSA and GEA have not identified any FDA regulation for aseptic packaging that expressly excludes the use of oxonia. To the extent that they point to any regulation at all, they invoke 21 U.S.C. § 178.005, which the Federal Circuit has already ruled is not limited to aseptic packaging, with the result that the requirements of that section do not limit the scope of the "FDA level of aseptic" (and therefore do not limit the scope of "aseptically disinfecting" as used in the patents-in-suit).

The PTAB construed the claims under the "broadest reasonable interpretation" rather than considering what a person of skill in the art would have understood at the time—the claim construction standard applied in district court under the Federal Circuit's *Phillips* case and its progeny. *Compare* old 37 C.F.R. § 42.100 (b) (effective May 2, 2016 to Nov. 12, 2018) ("A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification) *with* new 37 C.F.R. § 42.100 (b) (effective Nov. 13, 2018) ("[A] claim of a patent . . . shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent."); *see also generally Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc). But that difference in claim-construction standards does not affect the significance of the PTAB's decision for the issues currently before this Court. If the "broadest reasonable interpretation" of the "FDA level of aseptic" is not broad enough to encompass 21 U.S.C. § 178.005 (and other FDA regulations not limited to aseptic packaging), then, as a matter of logic, the even narrower *Phillips* construction of those words cannot be broad enough to encompass them.

Finally, it bears noting that in IPR proceedings, the PTAB may consider only questions of validity based on prior art in the form of patents and printed publications. The PTAB may not consider in IPR proceedings arguments based on failure to comply with the requirements of 35 U.S.C. § 112, such as lack of written description or lack of enablement. Arguments about written description were not and could not be presented to the PTAB in the IPR; therefore, the PTAB's decision should have no impact on this Court's evaluation of that issue.

Respectfully submitted,

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